115TH CONGRESS 2D SESSION

H. R. 5812

To amend the Public Health Service Act to authorize the Director of the Centers for Disease Control and Prevention to carry out certain activities to prevent controlled substances overdoses, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

May 15, 2018

Mr. Griffith (for himself, Mr. Pallone, and Mr. Fitzpatrick) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

- To amend the Public Health Service Act to authorize the Director of the Centers for Disease Control and Prevention to carry out certain activities to prevent controlled substances overdoses, and for other purposes.
 - 1 Be it enacted by the Senate and House of Representa-
 - 2 tives of the United States of America in Congress assembled,
 - 3 SECTION 1. SHORT TITLE.
 - 4 This Act may be cited as the "Creating Opportunities
 - 5 that Necessitate New and Enhanced Connections That
 - 6 Improve Opioid Navigation Strategies Act of 2018" or the
 - 7 "CONNECTIONS Act".

1	SEC. 2. PREVENTING OVERDOSES OF CONTROLLED SUB-
2	STANCES.
3	Part P of title III of the Public Health Service Act
4	(42 U.S.C. 280g et seq.) is amended by adding at the end
5	the following new section:
6	"SEC. 399V-7. PREVENTING OVERDOSES OF CONTROLLED
7	SUBSTANCES.
8	"(a) Evidence-Based Prevention Grants.—
9	"(1) In general.—The Director of the Cen-
10	ters for Disease Control and Prevention may—
11	"(A) to the extent practicable, carry out
12	any evidence-based prevention activity described
13	in paragraph (2);
14	"(B) provide training and technical assist-
15	ance to States, localities, and Indian tribes for
16	purposes of carrying out any such activity; and
17	"(C) award grants to States, localities, and
18	Indian tribes for purposes of carrying out any
19	such activity.
20	"(2) Evidence-based prevention activi-
21	TIES.—An evidence-based prevention activity de-
22	scribed in this paragraph is any of the following ac-
23	tivities:
24	"(A) With respect to a State, improving
25	the efficiency and use of the State prescription
26	drug monitoring program by—

1	"(i) encouraging all authorized users
2	(as specified by the State) to register with
3	and use the program and making the pro-
4	gram easier to use;
5	"(ii) enabling such users to access any
6	updates to information collected by the
7	program in as close to real-time as pos-
8	sible;
9	"(iii) providing for a mechanism for
10	the program to automatically flag any po-
11	tential misuse or abuse of controlled sub-
12	stances and any detection of inappropriate
13	prescribing practices relating to such sub-
14	stances;
15	"(iv) enhancing interoperability be-
16	tween the program and any electronic
17	health records system, including by inte-
18	grating the use of electronic health records
19	into the program for purposes of improving
20	clinical decisionmaking;
21	"(v) continually updating program ca-
22	pabilities to respond to technological inno-
23	vation for purposes of appropriately ad-
24	dressing a controlled substance overdose

1	epidemic as such epidemic may occur and
2	evolve;
3	"(vi) facilitating data sharing between
4	the program and the prescription drug
5	monitoring programs of neighboring
6	States; and
7	"(vii) meeting the purpose of the pro-
8	gram established under section 3990, as
9	described in section 399O(a).
10	"(B) Achieving community or health sys-
11	tem interventions through activities such as—
12	"(i) establishing or improving con-
13	trolled substances prescribing interventions
14	for insurers and health systems;
15	"(ii) enhancing the use of evidence-
16	based controlled substances prescribing
17	guidelines across sectors and health care
18	settings; and
19	"(iii) implementing strategies to align
20	the prescription of controlled substances
21	with the guidelines described in clause (ii).
22	"(C) Evaluating interventions to better un-
23	derstand what works to prevent overdoses, in-
24	cluding those involving prescription and illicit
25	controlled substances.

1	"(D) Implementing projects to advance an
2	innovative prevention approach with respect to
3	new and emerging public health crises and op-
4	portunities to address such crises, such as en-
5	hancing public education and awareness on the
6	risks associated with opioids.
7	"(b) Enhanced Surveillance of Controlled
8	SUBSTANCE OVERDOSE GRANTS.—
9	"(1) In General.—The Director of the Cen-
10	ters for Disease Control and Prevention may—
11	"(A) to the extent practicable, carry out
12	any controlled substance overdose surveillance
13	activity described in paragraph (2);
14	"(B) provide training and technical assist-
15	ance to States for purposes of carrying out any
16	such activity;
17	"(C) award grants to States for purposes
18	of carrying out any such activity; and
19	"(D) coordinate with the Assistant Sec-
20	retary for Mental Health and Substance Use to
21	collect data pursuant to section $505(d)(1)(A)$
22	(relating to the number of individuals admitted
23	to the emergency rooms of hospitals as a result
24	of the abuse of alcohol or other drugs).

1	"(2) Controlled substance overdose sur-
2	VEILLANCE ACTIVITIES.—A controlled substance
3	overdose surveillance activity described in this para-
4	graph is any of the following activities:
5	"(A) Enhancing the timeliness of reporting
6	data to the public, including data on fatal and
7	nonfatal overdoses of controlled substances.
8	"(B) Enhancing comprehensiveness of data
9	on controlled substances overdoses by collecting
10	information on such overdoses from appropriate
11	sources such as toxicology reports, autopsy re-
12	ports, death scene investigations, and other risk
13	factors.
14	"(C) Using data to help identify risk fac-
15	tors associated with controlled substances
16	overdoses.
17	"(D) With respect to a State, supporting
18	entities involved in providing information to in-
19	form efforts within the State, such as by coro-
20	ners and medical examiners, to improve accu-
21	rate testing and reporting of causes and con-
22	tributing factors to controlled substances

overdoses.

1	"(E) Working to enable information shar-
2	ing regarding controlled substances overdoses
3	among data sources.
4	"(c) Definitions.—In this section:
5	"(1) CONTROLLED SUBSTANCE.—The term
6	'controlled substance' has the meaning given that
7	term in section 102 of the Controlled Substances
8	Act.
9	"(2) Indian tribe.—The term 'Indian tribe'
10	has the meaning given that term in section 4 of the
11	Indian Self-Determination and Education Assistance
12	Act.
13	"(d) Authorization of Appropriations.—For
14	purposes of carrying out this section and section 3990,
15	there is authorized to be appropriated \$486,000,000 for
16	each of fiscal years 2019 through 2023.".
17	SEC. 3. PRESCRIPTION DRUG MONITORING PROGRAM.
18	Section 3990 of the Public Health Service Act (42
19	U.S.C. 280g-3) is amended to read as follows:
20	"SEC. 3990. PRESCRIPTION DRUG MONITORING PROGRAM.
21	"(a) Program.—
22	"(1) IN GENERAL.—Each fiscal year, the Sec-
23	retary, in consultation with the Director of National
24	Drug Control Policy, acting through the Director of
25	the Centers for Disease Control and Prevention, the

1	Assistant Secretary for Mental Health and Sub-
2	stance Use, and the National Coordinator for Health
3	Information Technology, shall support States for the
4	purpose of improving the efficiency and use of
5	PDMPs, including—
6	"(A) establishment and implementation of
7	a PDMP;
8	"(B) maintenance of a PDMP;
9	"(C) improvements to a PDMP by—
10	"(i) enhancing functional components
11	to work toward—
12	"(I) universal use of PDMPs
13	among providers and their delegates,
14	to the extent that State laws allow,
15	within a State;
16	"(II) more timely inclusion of
17	data within a PDMP;
18	"(III) active management of the
19	PDMP, in part by sending proactive
20	or unsolicited reports to providers to
21	inform prescribing; and
22	"(IV) ensuring the highest level
23	of ease in use and access of PDMPs
24	by providers and their delegates, to
25	the extent that State laws allow;

1	"(ii) improving the intrastate inter-
2	operability of PDMPs by—
3	"(I) making PDMPs more ac-
4	tionable by integrating PDMPs within
5	electronic health records and health
6	information technology infrastructure;
7	and
8	"(II) linking PDMP data to
9	other data systems within the State,
10	including—
11	"(aa) the data of pharmacy
12	benefit managers, medical exam-
13	iners and coroners, and the
14	State's Medicaid program;
15	"(bb) worker's compensation
16	data; and
17	"(cc) prescribing data of
18	providers of the Department of
19	Veterans Affairs and the Indian
20	Health Service within the State;
21	"(iii) improving the interstate inter-
22	operability of PDMPs through—
23	"(I) sharing of dispensing data in
24	near-real time across State lines; and

1	"(II) integration of automated
2	queries for multistate PDMP data
3	and analytics into clinical workflow to
4	improve the use of such data and ana-
5	lytics by practitioners and dispensers;
6	or
7	"(iv) improving the ability to include
8	treatment availability resources and refer-
9	ral capabilities within the PDMP.
10	"(2) State legislation.—As a condition on
11	the receipt of support under this section, the Sec-
12	retary shall require a State to demonstrate that the
13	State has enacted legislation or regulations—
14	"(A) to provide for the implementation of
15	the PDMP; and
16	"(B) to permit the imposition of appro-
17	priate penalties for the unauthorized use and
18	disclosure of information maintained by the
19	PDMP.
20	"(b) PDMP STRATEGIES.—The Secretary shall en-
21	courage a State, in establishing, improving, or maintaining
22	a PDMP, to implement strategies that improve—
23	"(1) the reporting of dispensing in the State of
24	a controlled substance to an ultimate user so the re-

- porting occurs not later than 24 hours after the dispensing event;
- "(2) the consultation of the PDMP by each prescribing practitioner, or their designee, in the State before initiating treatment with a controlled substance, or any substance as required by the State to be reported to the PDMP, and over the course of ongoing treatment for each prescribing event;
 - "(3) the consultation of the PDMP before dispensing a controlled substance, or any substance as required by the State to be reported to the PDMP;
 - "(4) the proactive notification to a practitioner when patterns indicative of controlled substance misuse by a patient, including opioid misuse, are detected;
 - "(5) the availability of data in the PDMP to other States, as allowable under State law; and
- "(6) the availability of nonidentifiable information to the Centers for Disease Control and Prevention for surveillance, epidemiology, statistical research, or educational purposes.
- 22 "(c) Drug Misuse and Abuse.—In consultation
- 23 with practitioners, dispensers, and other relevant and in-
- 24 terested stakeholders, a State receiving support under this
- 25 section—

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- "(1) shall establish a program to notify practitioners and dispensers of information that will help to identify and prevent the unlawful diversion or misuse of controlled substances; and
- 5 "(2) may, to the extent permitted under State 6 law, notify the appropriate authorities responsible 7 for carrying out drug diversion investigations if the 8 State determines that information in the PDMP 9 maintained by the State indicates an unlawful diver-10 sion or abuse of a controlled substance.
- 11 "(d) Evaluation and Reporting.—As a condition 12 on receipt of support under this section, the State shall 13 report on interoperability with PDMPs of other States and 14 Federal agencies, where appropriate, intrastate interoper-15 ability with health information technology systems such as electronic health records, health information exchanges, 16 17 and e-prescribing, where appropriate, and whether or not 18 the State provides automatic, up-to-date, or daily information about a patient when a practitioner (or the designee 19 of a practitioner, where permitted) requests information 21 about such patient.
- "(e) EVALUATION AND REPORTING.—A State receiving support under this section shall provide the Secretary with aggregate nonidentifiable information, as permitted by State law, to enable the Secretary—

1	"(1) to evaluate the success of the State's pro-
2	gram in achieving the purpose described in sub-
3	section (a); or
4	"(2) to prepare and submit to the Congress the
5	report required by subsection (i)(2).
6	"(f) Education and Access to the Monitoring
7	System.—A State receiving support under this section
8	shall take steps to—
9	"(1) facilitate prescribers and dispensers, and
10	their delegates, as permitted by State law, to use the
11	PDMP, to the extent practicable; and
12	"(2) educate prescribers and dispensers, and
13	their delegates on the benefits of the use of PDMPs.
14	"(g) Electronic Format.—The Secretary may
15	issue guidelines specifying a uniform electronic format for
16	the reporting, sharing, and disclosure of information pur-
17	suant to PDMPs.
18	"(h) Rules of Construction.—
19	"(1) Functions otherwise authorized by
20	LAW.—Nothing in this section shall be construed to
21	restrict the ability of any authority, including any
22	local, State, or Federal law enforcement, narcotics
23	control, licensure, disciplinary, or program authority,
24	to perform functions otherwise authorized by law.

1	"(2) Additional privacy protections.—
2	Nothing in this section shall be construed as pre-
3	empting any State from imposing any additional pri-
4	vacy protections.
5	"(3) Federal privacy requirements.—
6	Nothing in this section shall be construed to super-
7	sede any Federal privacy or confidentiality require-
8	ment, including the regulations promulgated under
9	section 264(c) of the Health Insurance Portability
10	and Accountability Act of 1996 (Public Law 104-
11	191; 110 Stat. 2033) and section 543 of this Act.
12	"(4) No federal private cause of ac-
13	TION.—Nothing in this section shall be construed to
14	create a Federal private cause of action.
15	"(i) Progress Report.—Not later than 3 years
16	after the date of enactment of the CONNECTIONS Act,
17	the Secretary shall—
18	"(1) complete a study that—
19	"(A) determines the progress of States in
20	establishing and implementing PDMPs con-
21	sistent with this section;
22	"(B) provides an analysis of the extent to
23	which the operation of PDMPs has—

1	"(i) reduced inappropriate use, abuse,
2	diversion of, and overdose with, controlled
3	substances;
4	"(ii) established or strengthened ini-
5	tiatives to ensure linkages to substance use
6	disorder treatment services; or
7	"(iii) affected patient access to appro-
8	priate care in States operating PDMPs;
9	"(C) determine the progress of States in
10	achieving interstate interoperability and intra-
11	state interoperability of PDMPs, including an
12	assessment of technical, legal, and financial
13	barriers to such progress and recommendations
14	for addressing these barriers;
15	"(D) determines the progress of States in
16	implementing near real-time electronic PDMPs;
17	"(E) provides an analysis of the privacy
18	protections in place for the information re-
19	ported to the PDMP in each State receiving
20	support under this section and any rec-
21	ommendations of the Secretary for additional
22	Federal or State requirements for protection of
23	this information;
24	"(F) determines the progress of States in
25	implementing technological alternatives to cen-

1	tralized data storage, such as peer-to-peer file
2	sharing or data pointer systems, in PDMPs and
3	the potential for such alternatives to enhance
4	the privacy and security of individually identifi-
5	able data; and
6	"(G) evaluates the penalties that States
7	have enacted for the unauthorized use and dis-
8	closure of information maintained in PDMPs
9	and the criteria used by the Secretary to deter-
10	mine whether such penalties qualify as appro-
11	priate for purposes of subsection (a)(2); and
12	"(2) submit a report to the Congress on the re-
13	sults of the study.
14	"(j) Advisory Council.—
15	"(1) ESTABLISHMENT.—A State may establish
16	an advisory council to assist in the establishment
17	improvement, or maintenance of a PDMP consistent
18	with this section.
19	"(2) Limitation.—A State may not use Fed-
20	eral funds for the operations of an advisory council
21	to assist in the establishment, improvement, or
22	maintenance of a PDMP.
23	"(3) Sense of congress.—It is the sense of
24	the Congress that, in establishing an advisory coun-

cil to assist in the establishment, improvement, or

- 1 maintenance of a PDMP, a State should consult 2 with appropriate professional boards and other inter-3 ested parties.
- "(k) Definitions.—For purposes of this section:
 - "(1) The term 'controlled substance' means a controlled substance (as defined in section 102 of the Controlled Substances Act) in schedule II, III, or IV of section 202 of such Act.
 - "(2) The term 'dispense' means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the internet or other means to effect such delivery.
 - "(3) The term 'dispenser' means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.
 - "(4) The term 'interstate interoperability' with respect to a PDMP means the ability of the PDMP to electronically share reported information with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

- "(5) The term 'intrastate interoperability' with respect to a PDMP means the integration of PDMP data within electronic health records and health information technology infrastructure or linking of a PDMP to other data systems within the State, including the State's Medicaid program, workers' compensation programs, and medical examiners or coroners.
 - "(6) The term 'nonidentifiable information' means information that does not identify a practitioner, dispenser, or an ultimate user and with respect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.
 - "(7) The term 'PDMP' means a prescription drug monitoring program that is State-controlled.
 - "(8) The term 'practitioner' means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which the individual practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

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"(9) The term 'State' means each of the 50 States, the District of Columbia, and any commonwealth or territory of the United States.

"(10) The term 'ultimate user' means a person who has obtained from a dispenser, and who possesses, a controlled substance for the person's own use, for the use of a member of the person's household, or for the use of an animal owned by the person or by a member of the person's household.

"(11) The term 'clinical workflow' means the integration of automated queries for prescription drug monitoring programs data and analytics into health information technologies such as electronic health record systems, health information exchanges, and/or pharmacy dispensing software systems, thus streamlining provider access through automated queries.".

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